FEB 5 2007

510 K SUMMARY

Date:	January 04, 2007
	Aspect Medical Systems, Inc.,
	One Upland Road, Norwood MA 02062
Contact Person:	Vikram Verma
	Phone: (617) 559-7134
	Fax: (617) 559-7948
Proprietary Name:	Zipprep Electrode
Common Name:	Electrode, Cutaneous Electrode
Classification:	Class II device. Refer to 21 CFR 882.1320
Product Code:	GXY
Predicate Devices:	Aspect Medical Systems Zipprep Electrode 510(k), # K940802, received FDA clearance on June 22, 1994.
	Aspect Medical Systems Zipprep EEG Sensor 510(k)#K961821, received FDA clearance on October 04, 1996.
Device Description:	The Zipprep Electrode is a single patient use, disposable pre-gelled electrode that is applied directly to the patient's forehead to record electro-physiological signals.
Indications for Use:	The Zipprep Electrode is applied directly to the patient's skin to enable recording of physiological signals.

Similarities and Differences:

Similarities:

- Same indications for use.
- Same intended use.
- Same fundamental scientific technology.
- Incorporates the same basic design.
- Biocompatible.

Differences:

The Zipprep Electrode has the following minor differences from the predicate device:

- Shape changed from "tear drop" to "rectangular".
- Stainless steel snap stud
- Polypropylene tape
- 18 month shelf life

Biocompatibility testing, in accordance with ISO10993, and electrical testing as per ANSI-AAMI EC12:2000 have been referenced to support the device.

In summary, the Zipprep Electrode is substantially equivalent to the predicate device. Aspect Medical Systems believes these modifications do not raise new questions of safety or effectiveness. The intended use is the same as the predicate device. The indications for use remain the same as the Zipprep Electrode and Sensor. The fundamental scientific technology remains the same as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aspect Medical Systems, Inc.
% Mr. Vikram Verma
Manager, Regulatory Affairs
and Quality Assurance
1 Upland Road
Norwood, Massachusetts 02062

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Re: K070069
Trade/Device Name: Zipprep Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: January 5, 2007
Received: January 8, 2007

Dear Mr. Verma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K070069

Device Name Zipprep Electrode

Indications For Use The Zipprep Electrode is applied directly to the patient's skin to enable recording of physiological signals.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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